VOLUME 5

STUDY TITLE

Bedoukian PMD Technical:
Waiver Request for the 90-Day Inhalation Toxicity Data Requirement

DATA REQUIREMENT

OCSPP Test Guideline: 870.3465

SPONSOR

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PREPARED BY

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COMPLETION DATE

September 13, 2019

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Submitter: Cinda L. Bell Date: 9/13/19

Cinda L. Bell
Agent for Bedoukian Research, Inc.

Bedoukian Research, Inc. (herein referred to as Bedoukian) is requesting a waiver of the 90-day inhalation toxicity data requirement (OCSPP 870.3465) for registration of their technical product, Bedoukian PMD Technical. Bedoukian PMD Technical contains 99.80% p-menthane-3,8-diol (i.e., PMD).

Per EPA's Preliminary Work Plan and Summary Document for p-menthane-3,8-diol, the 90-day inhalation toxicity study for PMD is not required because inhalable materials are not expected with PMD technical and manufacturing-use products; PMD has a vapor pressure of 1.36×10^{-2} mmHg. This document also concluded that the toxicological database is considered complete for characterizing hazard and assessing risk from PMD.

The Proposed Interim Registration Review Decision for PMD made the same conclusion as above and additionally stated that no additional studies are anticipated to be needed for registration review.

In addition, the 90-day inhalation toxicity study is only conditionally required for non-food uses. Per CFR footnote 8, the study is required if there is a likelihood of repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol. PMD is a powder that will not be applied as a gas, vapor, or aerosol so there will be no repeated inhalation exposure to humans. Therefore, this study is not required for this use.

Finally, no other registrants were required to submit the 90-day inhalation toxicity study to support registration of similar products; therefore, Bedoukian should also not be required to submit the study.

For the abovementioned reasons, Bedoukian is requesting a waiver of the 90-day inhalation toxicity data requirement (OCSPP 870.3465) to support registration of Bedoukian PMD Technical.